

Robert Cohen
560 Oradell Ave.
Oradell, NJ 07649
Tel: (201) 599-0325
Fax: (201) 599-0338

10/23/99 11:07 AM

October 21, 1999

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Dr.
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to revoke the regulation that approved *Posilac*, Monsanto's bovine growth hormone.

I respectfully request that FDA rescind their approval of Monsanto's *Posilac* and immediately remove it from the market, as **new evidence** demonstrates that the use of this powerful growth hormone poses serious health consequences for human consumers. In 1990, FDA regulators approved Monsanto's genetically engineered bovine growth hormone concluding that:

1. Levels of IGF-I in milk do not increase after rbGH/rbST (recombinant bovine somatotropin) treatment.

When that hormone is injected into cows, levels of IGF-I in milk increase by about 80% (*Science - Aug. 24, 1990 Juskevich & Guyer*).

2. Pasteurization destroyed the bovine growth hormone.

In fact, pasteurization at 162° F for thirty minutes only destroyed 19% of the bovine growth hormone. Milk is traditionally pasteurized for only 15 seconds - not thirty minutes (*Science - Aug. 24, 1990 Juskevich & Guyer*).

3. Human digestion destroyed protein hormones in milk and that there was no change in the human body resulting from milk consumption.

New evidence demands an immediate recall of this bovine growth hormone. Levels of IGF-I increase in the blood serum after humans consume milk.

99P-4613

CP 1

TIMELINE

1979

Twenty years ago, scientists discovered the most powerful growth hormone in the human body, naming it insulin-like growth factor-I (IGF-I).

1989

Ten years ago, scientists learned that IGF-I was an identical match in the cow's body and the human body.

1994

Five years ago, FDA encountered the biggest controversy in their history by approving the genetically engineered bovine growth hormone known as BGH.

1998

IGF-I has been called a key factor in the growth and proliferation of prostate cancer (*Science* - January 23, 1998, Vol. 279, p. 563 Chen) and breast cancer (*The Lancet* - May 9, 1998, Vol. 351, p. 1393, Hankinson).

1999

This year, IGF-I was identified as the key factor in the growth of lung cancer (*Journal of the National Cancer Institute* - January 20, 1999; Vol. 91, No.2, Yu).

THE NEW EVIDENCE

The current issue (October, 1999) of the *Journal of the American Dietetic Association* (Page 1231) said this about IGF-I levels in people who drink milk:

"Serum IGF-I levels (blood levels) increased significantly in the milk group . . . an increase of about 10% above baseline--but was unchanged in the control group."

This blockbuster scientific finding contradicts every major "zero withdrawal safety" conclusion reached by FDA. It is clear that hormones in milk survive digestion, and it is also clear that an increase of these hormones in milk from genetically engineered cows present a serious cancer risk to all consumers.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature _____

Name of Petitioner _____

Mailing Address _____

Telephone _____

Robert Cohen
560 Oradell Ave.
Oradell, NJ 07649
Tel: 201-599-0325
Fax: 201-599-0338

October 26, 1999

ENVIRONMENTAL IMPACT STATEMENT

I, Robert Cohen, respectfully request that my Citizen's Petition (Docket No. 99P-4613) be placed on an accelerated review process.

The consequences of *Posilac* present the most serious of health risks to all American milk and dairy consumers. New evidence reveals that a hormone in milk, IGF-I, is identical to human IGF-I. That hormone has been identified as a key factor in the growth and proliferation of breast cancer, prostate cancer, and lung cancer. It is now known that IGF-I levels in humans increases by a factor of 10% after milk consumption.

This new revelation contradicts previous FDA conclusions, and mandates immediate removal of Monsanto's *Posilac* from the market. To not do so would jeopardize the health and safety of American dairy consumers.

Sincerely,

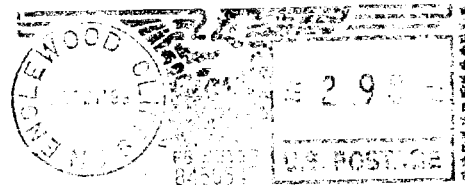


Robert Cohen

CERTIFIED

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MAIL



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